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EXAMINER

THALER, M

ART UNIT

PAPER NUMBER

33M1/0407

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3309

DATE MAILED:

04/07/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☐ This application has been examined ☒ Responsive to communication filed on 1-17-95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 18-36 are pending in the application.
Of the above, claims 19-22 are withdrawn from consideration.
2. ☒ Claims 1-17 have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 18, 23-36 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Claims 19-22 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in Paper No. 5.

Claims 18 and 23-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 18, line 2, it is suggested that "human" be inserted before "patient's" to make it clear that a human coronary artery is referred to. Also, in claim 18, line 13, "a" should be changed to "the". In claim 23, line 2, it is suggested that "human" be inserted before "patient's" to make it clear that a human coronary artery is referred to. Also, in claim 23, line 7, "a" should be changed to "the". It is suggested that all of the independent claims be amended similarly. In claim 24, paragraph d), line 4, "a" should be changed to "the" to make it clear that the "desired location" is the same location as defined earlier in the claim. In claim 31, it is not seen how the balloon is in communication with an exterior portion of the distal shaft section. In claim 33, line 2, "patient's which" is not understood. In claim 34, line 2, after "10", "cm" is missing.

Claims 24-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,040,548. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because it certainly would have been obvious to hold the portion of the guidewire which extends out of the proximal guidewire port (as defined in the application claims).

Claim 24 is rejected under 35 U.S.C. § 103 as being unpatentable over Enzmann et al. Enzmann et al. show catheter 50, distal guidewire opening 52, proximal guidewire opening 61, means 53 to perform an intravascular procedure which is spaced between the proximal and distal guidewire openings and guidewire 64. As to step d), Enzmann et al. show the step of introducing the catheter into the patient's vasculature over the guidewire (col. 12, lines 54-60), and then (after the guidewire is removed) advancing the catheter therein until the means 53 to perform an intravascular procedure is positioned within the patient's artery. It certainly would have been obvious to hold the portion of the guidewire which extends out of the proximal guidewire port while introducing the catheter in order to stabilize the assembly. Note that Enzmann et al. teach introducing the catheter into an artery as well as a vein (e.g. col. 10, lines 9-13).

Claim 24, 30-32 and 35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Uthmann. The Uthmann member 11 is a guidewire since it is elongated like a wire and since it guides catheter 12. Uthmann shows means 19 to perform an intravascular procedure.

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Alternatively, it would have been obvious that the Uthmann member 11 is a guidewire since it is elongated like a wire and since it guides catheter 12.

Claims 26 and 28 and 30-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Weikl et al. As to claim 26, note fig. 3 of Weikl et al. It would have been obvious that the Weikl et al. distal shaft section (at 14) is advancable within a patient's coronary arteries in view of the reference to "all types of blood vessels in col. 5, lines 65-68. As to claim 28, it would have been obvious that one of the lumens 12, 13 could be located in the Weikl et al. shaft 16 in the fig. 3 embodiment. The lumens 12, 13 are not shown in this embodiment. Therefore it is unclear whether they are located in member 1 or shaft 16. However, it is clear that the distal openings of these lumens must be located between the balloons in view of their function. Providing at least one of these lumens in the shaft 16 and sliding member 14 with the distal opening of the lumen extending to the distal end of sliding member 14 in order to be located between the balloons would have been obvious. As to claims 30-36, it would have been obvious that the Weikl et al. proximal guidewire opening (at the proximal end of slider 14) could be spaced proximally from the means to perform the procedure (balloon 5) in order to insure that the slider 14 would be long enough to slide smoothly over the guidewire 1.

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Claims 30-32 and 35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Gants. Gants shows catheter shaft 32, 30, balloon 28 and guidewire 12. The Gants catheter is inherently capable of being used in a patient's vasculature. Alternatively, it is obvious that the Gants catheter is inherently capable of being used in a patient's vasculature.

The declaration filed on Nov. 30, 1993 in parent application Serial No. 08/010,458 under 37 C.F.R. § 1.131 is sufficient to overcome the Bonzel reference.

Claims 18 and 23 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112, provided the suggestions made in paragraph 2 of this Office Action are made.

Claim 25 would be free of any prior art rejection provided the suggestions made in paragraph 2 of this Office Action are made.

Claims 27 and 29 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 (provided the suggestions made in paragraph 2 of this Office Action are made) and to include all of the limitations of the base claim and any intervening claims.

Applicant's arguments as well as the declaration filed Jan. 17, 1995 have been fully considered but they are not deemed to be persuasive for the reasons set forth above. The declaration filed under 37 C.F.R. 1.132 has been considered and given weight but the strong evidence of obviousness is considered to outweigh the

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evidence of unobviousness. The terminal disclaimer filed Jan. 17, 1995 fails to address the obviousness-type double patenting rejection based on Patent No. 5,040,548 which was patented before Patent No. 5,061,273.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981.

mht
February 28, 1995


MICHAEL THALER
PRIMARY EXAMINER
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